

NORTH DAKOTA PROTOCOL FOR PRESCRIBING TOBACCO CESSATION PRODUCTS

Adopted by the Board 11/18/2021

Pursuant to North Dakota Code 61-04-15, authorized pharmacists may prescribe medications for the purpose of tobacco cessation in accordance with this Protocol. Authorized pharmacists can implement the protocol as long as they follow the steps outlined below and provide a written order to the patient (or electronic prescription sent to the patient's pharmacy).

A. PURPOSE

This protocol specifies the criteria and procedures to assist pharmacists in providing safe and effective tobacco cessation therapy in North Dakota. This includes cessation of electronic nicotine delivery systems (i.e. "e-cigarettes" or other devices used for nicotine inhalation or nicotine dependence).

B. QUALIFICATIONS

To operate under the Protocol, the pharmacist must:

1. Have an active North Dakota pharmacist license;
2. Have completed a course of training approved by the Board of Pharmacy in the subject area of tobacco cessation drug therapy, in accordance to North Dakota Code 61-04-15-02; and
3. Be acting in good faith and exercising reasonable care based on current clinical best practices

C. PRODUCTS COVERED

Notwithstanding any other provision of law, a pharmacist may prescribe any FDA-approved medication with an indication for tobacco and/or smoking cessation, including the following:

1. Nicotine gum
2. Nicotine lozenge
3. Nicotine transdermal patch
4. Nicotine oral inhaler
5. Nicotine nasal spray
6. Bupropion SR oral tablets
7. Varenicline oral tablets

D. PROCEDURE

When a patient requests a medication for tobacco cessation, or when a pharmacist in his or her professional judgment decides to ask about tobacco use and offer to initiate tobacco cessation counseling and treatment, the pharmacist shall complete the following steps:

1. Informed Consent
 - a. The pharmacist shall ensure that verbal consent is received from the patient to provide care, and documented, per items 2-7 in this protocol.
2. Assessment
 - a. The pharmacist is encouraged to assess a patient's readiness to quit and apply the 5 A's approach for quitting: Ask, Advise, Assess, Assist, and Arrange, as described in the [Clinical Practice Guideline for Treating Tobacco Use and Dependence](#), or a similar strategy based on current evidence.
 - b. The pharmacist may offer tobacco cessation medication to tobacco users who are deemed ready to quit and provide tobacco cessation behavioral counseling and/or a referral to

counseling.

- c. The pharmacist may also offer tobacco cessation medications to tobacco users who are not deemed ready to quit, based on current evidence, and provide tobacco cessation behavioral counseling and/or referral to counseling.

3. Health Screening

- a. A health screening shall be performed and documented, and include at a minimum:
 - i. patient history, including medical and social history
 - ii. concurrent illness
 - iii. allergies and hypersensitivities
 - iv. medication history
- b. The pharmacist is encouraged to utilize and document a health screening procedure based on current clinical practice guidelines, to identify appropriate candidates for treatment by the pharmacist. Refer to the appendix for an example health screening questionnaire.

4. Referral of high-risk patients

- a. The pharmacist shall assess and consult with or refer high-risk patients to a primary care provider, psychiatrist, or other provider, as appropriate. For purposes of this protocol, high-risk is defined as any contraindication to a tobacco cessation medication according to current evidence/literature/practice guidelines. Patients who are pregnant, or planning to become pregnant in the next 3 months, are also considered high-risk patients.

5. Dispensing eligible products

- a. The pharmacist, in consultation with the patient, may select and dispense any tobacco cessation medication approved by the FDA (alone or in combination).
- b. Combination therapy (e.g., the nicotine patch plus nicotine gum, lozenge, inhaler or nasal spray; varenicline plus nicotine replacement therapy; varenicline plus bupropion SR; or bupropion SR plus nicotine replacement therapy) may be used, per current clinical practice guideline recommendations and/or published peer-reviewed literature recommendations, and is acceptable as appropriate based on patient needs and preferences.

6. Counseling

- a. The patient should be encouraged to ask questions and will be supplied with educational material on any therapies dispensed.
- b. Pharmacists shall provide appropriate behavioral counseling and/or refer the patient to other resources for assistance, including but not limited to the state quitline program (telephone online registration, or by fax/electronic referral).
- c. When a tobacco cessation product is dispensed under the protocol, the pharmacist shall provide necessary information about the product pursuant to North Dakota Code 43-15-31.2.

7. Follow-up

- a. To reassess the appropriateness and/or continuation of therapy, pharmacists are encouraged to follow up with patients:
 - i. Within two weeks of initiating therapy
 - ii. After completion of a course of therapy

E. NOTIFICATION

As soon as reasonably possible, the authorized pharmacist shall notify the patient's primary health care provider of the tobacco cessation therapy provided to the patient. If the patient does not have a primary health care provider, the pharmacist may provide the patient with a record of the tobacco cessation therapy provided and shall advise the patient to consult a practitioner, pursuant to North Dakota Code 61-04-15-02.

F. DOCUMENTATION

1. An authorized pharmacist shall maintain records of the care provided (including the health screening) and any tobacco cessation products ordered and dispensed pursuant to this protocol. All records will be maintained for 5 years.
2. A copy shall be made available to the patient and/or patient's provider upon request.

PHARMACIST TOBACCO CESSATION SCREENING QUESTIONNAIRE EXAMPLE

Name _____ Date of Birth _____ Today's Date _____

Best Phone Contact Number: _____

Primary Care Provider: _____

Social and Medical History:

Are you currently using cigarettes? Yes / No

- If yes, how many per day? _____ How many years? _____

Are you currently using other forms of nicotine or tobacco (chewing/snuff tobacco, cigars, pipe tobacco, vaping/electronic nicotine delivery devices)? Yes / No

- If yes, which product(s)? _____ How much/how many per day? _____
How many years? _____

Do you have a planned quit date? Yes/No If yes, when? _____

Have you previously tried to quit smoking? Yes/No If so, how many times? _____

Methods tried? _____

Have you previously tried to quit smoking using medication(s)? Yes / No

- If medications were used, please list them and any outcomes of treatment (adverse effects/efficacy):

Please list any medical problems or health conditions:

Allergies or sensitivities to medications? Yes / No If yes, list them here : _____

If you are taking any medications (including OTC/herbals/vitamins), list them here with strength and directions:

Are you interested in trying a specific medication for tobacco cessation?

- | | |
|--|--|
| <input type="checkbox"/> Nicotine products (gum, lozenge, patch, nasal spray, inhaler) | <input type="checkbox"/> Bupropion SR (formerly Zyban) |
| <input type="checkbox"/> Varenicline (Chantix) | <input type="checkbox"/> Combinations of medications |
| <input type="checkbox"/> Unsure / No preference | |

Specific Medical History:

<i>Specific Medical History:</i>		
1	Are you under 18 years of age?	Yes <input type="checkbox"/> No <input type="checkbox"/>
1	Are you pregnant or are you planning on becoming pregnant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	Do you have a history of seizures (also called epilepsy)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
3	Do you have, or have you ever had, an eating disorder (anorexia, bulimia)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
4	Do you have an history of mental illness or a psychiatric disorder? (examples include anxiety, depression, bipolar disorder, manic/depressive disorder, schizophrenia, etc).	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Have you ever had any bad reactions to nicotine replacement therapy, bupropion (Zyban/Wellbutrin) or varenicline (Chantix)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6	Are you currently taking (or taken within the past 14 days) any medications for depression called "MAO-inhibitors" which may include isocarboxazid (Marplan), phenelzine (Nardil), rasagiline (Azilect), selegiline (Emsam) or tranylcypromine (Parnate)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Have you had a heart attack within 14 days or do you have any history of heart electrical problems (called "arrhythmias") or severe or worsening chest pains (called "angina")?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you have any known medical conditions or problems with your kidneys (called "renal impairment or failure") or your liver (called "hepatic impairment or failure")?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Have you recently stopped using any seizure medications or sedative medications (also called barbiturates or benzodiazepines) or <u>planning to stop</u> using them?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Have you recently abruptly stopped using alcohol or <u>planning to stop</u> using alcohol?	Yes <input type="checkbox"/> No <input type="checkbox"/>

This section for pharmacist use:

- Verified patient DOB
- Patient Not Eligible (Explain reason for being ineligible for tobacco cessation medication use)
- Medication Prescribed per Protocol
- Behavioral Treatment/Counseling Provided:
 - Referred to ND Quits (or other state quitline program)
 - Referred to local tobacco cessation counseling program
 - In-house tobacco cessation counseling provided
 - Other (specify):

Rx #:

Medication Prescribed:

Sig:

Pharmacist Prescriber Name and Signature

Attention Pharmacy: This is a template document. Please feel free to customize it to your particular pharmacy, however documentation must reflect care provided as set forth in section D of this protocol. Electronic versions may be developed as appropriate if data elements are maintained and pharmacist user can be tracked.